

**REMARKS**

Claims 3-4, 12-18 and 20-22 stand rejected under 35 USC Section 103 as being unpatentable over Evenden *et al.*, WO/05/11891. Claims 23-33 have been added. The language for support of the newly added claims can be found at page 1, lines 21-22, page 1, line 28 to page 2 line 3; page 2, lines 5, 11, 17-18; page 3, line 20 and the originally filed claims. Claims 3-5, 12-18, 20-22 and 23-33 are pending in the application.

The Examiner states that Evenden *et al.* teach similar compounds with the same general formula and that the difference between the invention as described by the pending claims is in the generic description of the compounds and that the indiscriminate selection of "some" among "many" is *prima facie* obvious and that the motivation to make the invention as described in the pending claims is to make additional useful compounds.

Applicants respectfully traverse the rejection.

In order for an invention to be obvious, there must be suggestion or motivation in the prior art to make the invention. Here, one of ordinary skill in the art would have to be motivated to choose the tartrate salt and to further choose the monohydrate over the numerous salts that could be made. In order for one of ordinary skill in the art to be motivated to choose the salts, there must either be a suggestion in the prior art to make a salt that is stable, with good solubility and dissolution properties or a suggestion to make the monohydrate.

Although Evenden *et al.* mentions "tartatic acids", there is no guidance or motivation to lead a worker to come up with a salt that has the improved physical properties noted above. Further there is no suggestion that would allow one of ordinary skill in the art to attain the monohydrate.

A *prima facie* case of obviousness has therefore not be established. Applicants respectfully note that, the Examiner has, at the most, only established a suggestion to try a tart rate salt. But a suggestion to try something is not the test for obviousness. The suggestion to try must provide a reasonable expectation of success. The Examiner will appreciate that there is no guidance in Evenden *et al.*, or any other reference, to lead a

worker to attain a tartrate salt that is physically stable, has good dissolution properties and which has good solubility. Nor does the prior art provide any guidance to a worker of ordinary skill in the art to make the monohydrate.

Assuming for the moment that the Examiner has established a *prima facie* case of obviousness, the applicants respectfully submit that they have rebutted the *prima facie* case by presenting objective evidence of secondary considerations such as unexpected and surprising results. The Examiner must consider the objective criteria in the Examiner's determination of obviousness. Evidence of surprising and unexpected results of stability for example has supported patentability on numerous occasions in the patent office. Here, the evidence shows that for the monohydrate form of the salt, water is firmly bound in the crystal lattice and that the monohydrate does not convert to the dihydrate or trihydrate with increasing percent relative humidity. *See Figure 2*. The Examiner will further appreciate that it is not suggested or predicted that the monohydrate form of the tartrate salt would be less hygroscopic than other forms.

Applicants further submit that the patent office regularly allow and issue claims directed to new forms of "old" compounds when the applicants present experimental data showing unexpected advantage of the new form for example by showing that the form is thermodynamically stable than other forms. The Examiner may review the following patents for guidance:

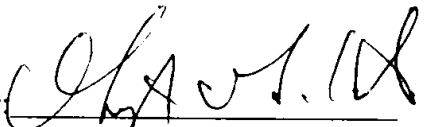
- US 5,872,132 (forms of paroxetine);
- US 5,412,095 (forms of terazosin);
- US 4,521,431 (form of rantidine);
- US 4,160,863 and US 4,504,657 (forms of cefadroxil);
- US 5,424,471 (crystalline amifostine, product-by-process claims);
- US 5,015,646, 4,812,561, 4,624,928, 4,467,086, 4,537,959 and 4,006,138 (forms of cephalosporin);
- US 3,932,386 (form of penicillin).

Many cases both at the Federal Circuit and District levels have upheld the validity of patents directed to new salt forms of old compounds.

In view of the above comments and remarks, Applicant respectfully submits that the invention as describe in the pending claims is patentable. Accordingly, reconsideration and allowance is earnestly requested.

Respectfully submitted,

Dated: December 31, 2002

By   
George A. Gilbert  
Registration No.: 35,881

In re Patent Application of: Nyqvist et al.  
Title: A New Salt  
Serial No.: 09/077,718      Filing Date: June 8, 1998

**Receipt is hereby acknowledged for the following in  
the United States Patent and Trademark Office:**

**CONTENTS:**      Transmittal Letter in duplicate (2 pages);  
Petition to Withdraw Abandonment (2 pages); Copy of Continued  
Prosecution Application (CPA); and Amendment (5 pages).

*Power of Attorney / RATIFICATION BY  
INVENTORS (2 pages)*

Mailed: Dec 31, 2002    Docket No.: 1747-1  
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